

7. REGULATIONS AND ADVISORIES

The international, national, and state regulations and guidelines regarding methylene chloride in air, water, and other media are summarized in Table 7-1.

The International Agency for Research on Cancer (IARC) classifies methylene chloride as a Group 2B carcinogen (possibly carcinogenic to humans) (IARC 1987). The Department of Health and Human Services (DHHS) has determined that methylene chloride may reasonably be anticipated to be a carcinogen. The National Institute for Occupational Safety and Health has listed methylene chloride as a possible human carcinogen (NIOSH 1997).

OSHA requires employers of workers who are occupationally exposed to methylene chloride to institute engineering controls and work practices to reduce and maintain employee exposure at or below permissible exposure limits (PEL). The employer must use engineering and work practice controls, if feasible, to reduce exposure to or below an 8-hour TWA of 25 ppm (OSHA 1998a, 1998b). Respirators must be provided and used during the time period necessary to install or implement feasible engineering and work practice controls, or where controls are not yet sufficient. Respirators are also required when the employer determines that compliance with the TWA or PEL is not feasible with engineering or work practice controls, such as maintenance and repair activities, vessel cleaning, or other operations where exposures are intermittent and limited in duration, and in emergencies (OSHA 1987).

The EPA has calculated a chronic oral reference dose (RfD) of 0.06 mg/kg/day for methylene chloride based on a NOAEL of approximately 6 mg/kg/day for rats in a 2-year drinking water bioassay (IRIS 1999; Serota et al. 1986a). The critical effect was liver toxicity. ATSDR has calculated an acute inhalation MRL of 0.6 ppm based on a LOAEL of 300 ppm in an acute study in humans that evaluated the effects of methylene chloride on the central nervous system (Winneke 1974). This MRL supersedes the previous acute inhalation MRL of 3 ppm derived in the 1998 draft for public comment version of this profile. In the new derivation of this MRL, a PBPK model (Reitz et al. 1997) was applied to adjust the dosage yielding an adjusted LOAEL of 60 ppm. An intermediate-duration inhalation MRL of 0.3 ppm was calculated based on a 100-day inhalation study in rats that identified a LOAEL of 25 ppm for liver effects (Haun et al. 1972). A chronic inhalation MRL of 0.3 ppm was calculated based on a NOAEL of 50 ppm for liver effects (Nitschke et al. 1988a). Using a PBPK model for inhalation-to-oral extrapolation of the Winneke (1974) data, an acute oral MRL of 0.2 mg/kg/day was calculated, based on a LOAEL of

7. REGULATIONS AND ADVISORIES

16 mg/kg/day for neurological effects (Reitz et al. 1997). This MRL supersedes the previous acute oral MRL of 0.5 mg/kg/day published in the 1998 draft for public comment version of this profile. In the new derivation, the uncertainty factor for human variability was increased from 3 to 10. ATSDR has also calculated a chronic oral MRL of 0.06 mg/kg/day based on a NOAEL of 6 mg/kg/day for liver effects (Serota et al. 1986a). This MRL supersedes the previous chronic oral MRL of 0.2 mg/kg/day published in the 1998 draft for public comment version of this profile. In the new derivation, the uncertainty factor for extrapolation from animals to humans was increased from 3 to 10.

7. REGULATIONS AND ADVISORIES

Table 7-1. Regulations and Guidelines Applicable to Methylene Chloride

Agency	Description	Information	References
<u>INTERNATIONAL</u>			
IARC	Carcinogenic classification	Group 2B ^a	IARC 1987
<u>NATIONAL</u>			
Regulations:			
a. Air:			
ACGIH	TLV-TWA	50 ppm	ACGIH 1999
NIOSH	REL	Lowest feasible concentration	NIOSH 1999
OSHA	PEL 8hr-TWA STEL determined over a 15 minute sampling period	25 ppm 125 ppm	29 CFR 1910.1052 OSHA 1999
b. Water:			
EPA	MCL applying to community and non-transient, non-community water systems	0.005 mg/L	40 CFR 141.61 EPA 1999g
	MCLG	Zero	40 CFR 141.50 EPA 1999f
	Health Advisories		EPA 1996a
	1-day (10-kg child)	10 mg/L	
	10-day (10-kg child)	2 mg/L	
	Longer-term child	ND ^b	
	Longer-term adult	ND	
	DWEL	2 mg/L	
	Water Quality Criteria water + organisms organisms only	4.7 µg/L 1600 µg/L	EPA 1999j
c. Food:			
EPA	Indirect food additive: ingredient in pesticide formulations as a solvent used on growing crops	No tolerance limit when used as an inert ingredient	40 CFR 180.1001 EPA 1999i
	Exemption from tolerance for fumigant uses	Yes	40 CFR 180.1010 EPA 1998b
FDA	Ban on use of methylene chloride in cosmetic products	Yes	21 CFR 700.19 FDA 1999c

7. REGULATIONS AND ADVISORIES

Table 7-1. Regulations and Guidelines Applicable to Methylene Chloride (continued)

Agency	Description	Information	References
FDA (contd)			
	Methylene chloride present in foods with the following limits:		21 CFR 173.255 FDA 1999b
	Spice oleoresins, residue	30 ppm	
	Limit in hops extract	2.2%	
	Hops extract, residue	5 ppm	
	Decaffeinated roasted coffee and soluble coffee extract (instant coffee)	10 ppm	
	Indirect food additive component of adhesives used in food packaging or transporting	Yes	21 CFR 175.105 FDA 1999a
	Indirect food additive: used in the production of polycarbonate resins which are used for food packaging and transport	Yes	21 CFR 177.1580 FDA 1999d
	Indirect food additive: used in ink for marking fruits and vegetables	Yes	21 CFR 73.1 FDA 1999e
d. Other:			
ACGIH	Carcinogenic classification	A3 ^c	ACGIH 1999
	Biological Exposure Indices		
	Methemoglobin in blood	1.5% of hemoglobin	
EPA	RfD (oral)	6×10^{-2} mg/kg/day	IRIS 1999
	Carcinogen Classification	Group B2 ^d	
	Cancer slope factor (q1*)	7.5×10^{-3} (mg/kg)/day	
	Inhalation unit risk	4.7×10^{-7} ($\mu\text{g}/\text{m}^3$) ⁻¹	
	Reportable quantity for hazardous substances	1,000 lbs	40 CFR 302.4 EPA 1999a
	Methylene chloride - designated CERCLA hazardous substance under sections 307(a) of the Clean Water Act and RCRA section 3001		
	Toxic Chemical Release Reporting— effective date	1/1/87	40 CFR 372.65 EPA 1999b
	Identification and listing as a hazardous waste	Yes	40 CFR 261.33 EPA 1999c

7. REGULATIONS AND ADVISORIES

Table 7-1. Regulations and Guidelines Applicable to Methylene Chloride (continued)

Agency	Description	Information	References
d. Other:			
EPA (contd)			
	List of toxic pollutants designated pursuant to section 307(a)(1) of the Act	Yes	40 CFR 401.15 EPA 1998h
OSHA	Inhalation Unit Risk	$3.62 \times 10^{-3} (\mu\text{g}/\text{m}^3)^{-1}$	OSHA 1997
USC	List of hazardous air pollutants	Yes	42 USC 7412 USC 1999
	Universal treatment standards wastewater non-wastewater	0.089 mg/L 30 mg/L	40 CFR 268.48 EPA 1999d
<u>STATE</u>			
Regulations and guidelines:			
a. Air:			
Idaho	Acceptable ambient concentration for a carcinogen	$2.4 \times 10^{-1} \mu\text{g}/\text{m}^3$	ID Dept Health Welfare 1999
Kansas	Concentration limits for hazardous air emissions	10 tons/year	KS Dept. Health Env 1998
Massachusetts	Acceptable ambient air concentrations	$0.24 \mu\text{g}/\text{m}^3$ (annual)	MA Dept. Env. Protect. 1998
New Jersey	Acceptable ambient air concentrations	$4.7 \times 10^{-7} \mu\text{g}/\text{m}^3$	NJ Dept Env. Protect. 1998
New York	Acceptable ambient air concentrations	$27.0 \mu\text{g}/\text{m}^3$ (annual)	NY Dept. Env. Conserv. 1998
North Carolina	Acceptable ambient air concentrations	$2.4 \times 10^{-2} \text{mg}/\text{m}^3$ (annual)	NC Div. Env. Manage. 1998
Rhode Island	Acceptable ambient air concentrations	$2.0 \mu\text{g}/\text{m}^3$ (annual)	RI Dept. Env Management 1992
Vermont	Acceptable ambient air concentrations	$0.02 \mu\text{g}/\text{m}^3$ (annual)	VT Nat. Res. Agency 1998
Washington	Acceptable ambient air concentrations	$2.0 \mu\text{g}/\text{m}^3$ (annual)	WA Dept. Ecology 1998
Wisconsin	Acceptable emission levels <25 feet 25 feet	29 lbs/hr 122 lbs/hr	WI Dept Natural Resources 1997

7. REGULATIONS AND ADVISORIES

Table 7-1. Regulations and Guidelines Applicable to Methylene Chloride (continued)

Agency	Description	Information	References
b. Water.			
Alabama	Human health criteria for the consumption of: water and organism ^e organism only ^e	3.4x10 ⁻⁴ µg/L 1.48x10 ⁻² µg/L	AL Dept Env Management 1998
Alaska	Maximum contaminant level	0.005 mg/L	AK Dept Env Conserv 1999
New Jersey	Ground water quality	2 µg/L	NJ Dept Env Protec 1993
Oklahoma	Ground water quality criteria	10.0 µg/L	OK Dept Env Quality 1997
South Dakota	Maximum contaminant levels— apply to community and non-transient and non-community water systems	0.005 mg/L	SD Dept Env Natural Resources 1998

^a: Group 2B - The agent is possibly carcinogenic to humans

^b: ND - Not data

^c: A3 - Confirmed animal carcinogen with unknown relevance to humans

^d: B2 - Probable human carcinogen

^e: The following equations were used to calculate the values as given in the Alabama State laws:

Consumption of water and organism:

$$\text{Concentration (mg/l)} = (\text{HBW} \times \text{RL}) / (\text{CPF} \times [(\text{FCR} \times \text{BCF}) + \text{WCR}])$$

Consumption of organism only:

$$\text{Concentration (mg/l)} = (\text{HBW} \times \text{RL}) / (\text{CPF} \times \text{FCR} \times \text{BCF})$$

HBW = human body weight, set at 70 kg

RL = risk level, set at 1×10^{-5}

CPF = cancer potency factor, 0.0075 (kg-day)/mg

FCR = fish consumption rate, set at 0.030 kg/day

BCF = bioconcentration factor, 0.9 L/kg

WCR = water consumption rate, set at 2 L/day

ACGIH = American Conference of Governmental Industrial Hygienists; DWEL = drinking water equivalent level; EPA = Environmental Protection Agency; FDA = Food and Drug Administration; IARC = International Agency for Research on Cancer; IRIS = Integrated Risk Information System; MCL = maximum contaminant level; MCLG = maximum contaminant level goal; NIOSH = National Institute of Occupational Safety and Health; OSHA = Occupational Safety and Health Administration; PEL = permissible exposure limit; REL = recommended exposure release; RfD = reference dose; TLV = threshold limit value; TWA = time-weighted average